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Application Number	10/773706
Filing Date	12/11/2003
First Named Inventor	Acsadi et al.,
Group Art Unit	
Examiner Name	
Attorney Docket Number	48.01

Total Number of Pages in This Submission **109**

ENCLOSURES (check all that apply)

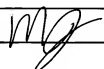
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Acsadi et al.,)
Serial No.: 10/773706)
Filed: 12/11/2003)
Group Art Unit:)

For: COMPOSITIONS AND METHODS FOR DRUG DELIVERY USING pH
SENSITIVE MOLECULES

INFORMATIONAL STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. 1.56, applicant hereby calls to the attention of the Patent and Trademark Office the publications listed on the attached PTO 1449. One copy of each publication is attached.

UNITED STATES PATENTS

<u>Patent No.</u>	<u>Inventor</u>	<u>Issue Date</u>
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FOREIGN PATENTS

<u>Patent No.</u>	<u>Inventor</u>	<u>Issue Date</u>
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REFERENCES CITED

Acsadi et al., "Direct gene transfer and expression into rat heart in vivo," The New Biologist; 1991, vol. 3, no.1, pp. 71-81

Budker et al., "The efficient expression of intravascularly delivered DNA in rat muscle," Gene Therapy; 1998, vol. 5, pp. 272-276.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.M./

Chapman et al., "Gene transfer into coronary arteries of intact animals with a percutaneous balloon catheter," *Circulation Research*; 1992, vol.71, no. 1, pp. 27-33

Chowdhury et al., "Long-term improvement of hypercholesterolemia after ex vivo gene therapy in ldlr-deficient rabbits," *Science*; 1991, vol. 254, pp. 1802-1805

Ferry et al., "retroviral-mediated gene transfer into hpatocytes in vivo," *Proc. Natl. Acad. Sci. USA*; 1991, vol. 88, pp. 8377-8381

Greelish et al., "stable restoration of the sarcologycan complex in dystrophic muscle perfused with histamine and a recombinant adeno-associated viral vector," *Nature Medicine*; 1999, vol. 5, no. 4, pp. 439-443

Grossman et al., "successful ex vivo gene therapy directed to liver in a patient with familial hypercholesterolaemia," *Nature Genetics*; 1994, vol. 6, pp. 335-341

Hengge et al., "Cytokine gene expression in epidermis with biological effects following injection of naked dna," *Nature Genetics*; 1995, vol. 10, pp. 161-166

Hickman et al., "Gene expression following direct injection of dna into liver," *Human Gene Therapy*; 1994, vol. 5, pp. 1477-1483

Jaffe et al., "Adenovirus-mediated in vivo gene transfer and expression in normal rat liver," *Nature Genetics*; 1992, vol. 1, pp. 372-378

Kaleko et al., "Persistent gene expression after retroviral gene transfer into liver cells in vivo," *Human Gene Therapy*; 1991, vol. 2, pp. 27-32

Kaneda et al., "Increased expression of dna cointroduced with nuclear protein in adult rat liver," *Science*; 1989, vol. 243, pp. 375-378

Kaneda et al., "Introduction and expression of the human insulin gene in adult rat liver," *The Journal of Biological Chemistry*; 1989, vol. 264, no. 21, pp. 12126-12129

Kay et al., "Hepatic gene therapy: persistent expression of human a1-antitrypsin in mice after direct gene delivery in vivo," *Human Gene Therapy*; 1992, vol. 3, pp. 641-647

Ledley et al., "Retroviral gene transfer into primary hepatocytes: implications for genetic therapy of liver-specific functions," *Proc. Natl. Acad. Sci. USA*; 1987, vol. 84, pp. 5335-5339

Li et al., "Assessment of recombinant adenoviral vectors for hepatic gene therapy," Human Gene Therapy; 1993, vol. 4, pp. 403-409

Liu et al., "Hydrodynamics-based transfection in animals by systemic administration of plasmid dna," Gene Therapy; 1999, vol. 6, pp. 1258-1266

Malone et al., "Dexamethasone enhancement of gene expression after direct hepatic dna injection," The Journal of Biological Chemistry; 1994, vol. 269, no. 47, pp. 29903-29907

Meyer et al., "Intracheal gene delivery to the mouse airway: characterization of plasmid DNA expression and pharmacokinetics," Gene Therapy; 1995, vol. 2, pp. 450-460

Milas et al., "Isolated limb perfusion in the sarcoma-bearing rat: a novel preclinical gene delivery system," Clinical Cancer Research; 1997, vol. 3, pp. 2197-2203

Riessen et al., "Arterial gene transfer using pure dna applied directly to a hydrogel-coated angioplasty balloon," Human Gene Therapy; 1993, vol. 4, pp. 749-758

Sikes et al., "In vivo gene transfer into rabbit thyroid follicular cells by direct dna injection," Human Gene Therapy; 1994, vol. 5, no. 837-844

Soriano et al., "Targeted and nontargeted liposomes for in vivo transfer to rat liver cells of a plasmid containing the preproinsulin I gene," Proc. Natl. Acad. Sci. USA; 1983, vol. 80, pp. 7128-7131

Stratford-Perricaudet et al., "Evaluation of the transfer and expression in mice of an enzyme-encoding gene using a human adenovirus vector," Human Gene Therapy; 1990, vol. 1, pp. 241-256

Vile et al., "Use of tissue-specific expression of the herpes simplex virus thymidine kinase gene to inhibit growth of established murine melanomas following direct intratumoral injection of dna," Cancer Research; 1993, vol. 53, pp. 3860-3864

Wolff et al., "Direct gene transfer into mouse muscle in vivo," Science; 1990, vol. 247, pp. 1465-1468


Wolff et al., "Expression of retrovirally transduced genes in primary cultures of adult rat hepatocytes," Proc. Natl. Acad. Sci. USA; 1987, vol. 84, pp. 3344-3348

Yang et al., "Immune responses to viral antigens versus transgene product in the elimination of recombinant adenovirus-infected hepatocytes in vivo," Gene Therapy; 1996, vol. 3, pp. 137-144

Zhang et al., "efficient expression of naked dna delivered intraarterially to limb muscles of nonhuman primates," Human gene therapy; 2001, vol. 12, pp. 427-438

Zhang et al., "High levels of foreign gene expression in hepatocytes after tail vein injections of naked plasmid dna," Human Gene Therapy; 1999, vol. 10, pp. 1735-1737

Respectfully submitted,



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**INFORMATION DISCLOSURE
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FORM PTO-1449

Attorney Docket No.:

Mirus.048.01

Serial No.: 10/773706

Applicant: **Acsadi et al.,**

Group:

Examiner:

U.S. PATENT DOCUMENTS

Exmnr Intl	Seq	Patent Number	Issue Date	Patentee	Class	Sub Class	Filing Date
							12/11/2003

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION


		Document Number	Publ. Date	Country or Patent Office	Class	Sub Class	Transl. Yes	No

OTHER DOCUMENTS (Including Author, Title, Date Pertinent Pages, etc.)

	Acsadi et al., "Direct gene transfer and expression into rat heart in vivo," The New Biologist; 1991, vol. 3, no.1, pp. 71-81
	Budker et al., "The efficient expression of intravascularly delivered DNA in rat muscle," Gene Therapy; 1998, vol. 5, pp. 272-276.
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/Manuel Mendez/

07/16/2008